Docket No.: NEN-22402/16 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: Lucille Beaudet et al.

Application No.: 10/563,047 Confirmation No.: 6066

Filed: July 2, 2004 Art Unit: 1797

For: SCINTILLATOR COMPOSITION FOR A RADIOASSAY, AND METHOD FOR ITS USE Examiner: X. Xu

APPELLANT'S APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party in interest in this case is Perkinelmer LAS, Inc., by assignment.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 27 claims. Claims 2, 8, 10, 13, 17 and 26 have been canceled. Claims 1, 3-7, 9, 11, 12, 14-16, 18-25 and 27 are pending, rejected and under appeal. Claims 1, 9, 16 and 25 are the independent claims.

IV. Status of Amendments

No after-final amendments have been filed.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to a medium for a scintillation assay, said medium comprising a solid body comprising a first scintillator material, wherein the first scintillator material is a fluorescent Coumarin dye having a Stokes shift of at least 50 nm, wherein the fluorescent emission of the solid body comprising the first scintillator material is in the range of 460-500 nm. (Specification, page 3, line 28 – page 4, line 1; and page 6, lines 10-24, inter alia).

Independent claim 9 is directed to a method for carrying out an assay for detecting or quantifying a radio nuclide emission, said method comprising the steps of providing a scintillation medium comprising a solid body which contains a first scintillator material which is a Coumarin dye having a Stokes shift of at least 50 nm, wherein the fluorescent emission of the solid body which contains a Coumarin dye is in the range of 460-500 nm; contacting said scintillation medium with an analyte suspected of having said radionuclide therein; and detecting any scintillation caused in said medium by said radionuclide. (Specification, page 1, lines 7-12; page 3, line 28 – page 4, line 1; page 6, lines 10-30; and Figures 5 and 6, inter alia).

Independent claim 16 is directed to a solid state member for a scintillation proximity assay, said member comprising a polymeric material having a first scintillator material which is a fluorescent Coumarin dye incorporated therein, said Coumarin dye further characterized in that it has a Stokes shift of at least 50 nm, wherein said solid state member has a fluorescent emission in the range of 460-500 nm. (Specification, page 3, line 28 – page 4, line 1; and page 6, lines 10-24, inter alia).

Independent claim 25 is directed to a liquid scintillation cocktail comprising a first scintillator material which is a fluorescent Coumarin dye having a Stokes shift of at least 50 nm; a second scintillator material selected from the group consisting of: PPO, bis-MSB, DPA, combinations thereof; and a solvent for said first and second scintillator materials, wherein said liquid scintillation cocktail has a fluorescent emission in the range of 460-500 nm. (Specification, page 3, line 28 – page 4, line 1; page 5, lines 4-24; and page 6, lines 10-24, inter alia).

VI. Grounds of Rejection To Be Reviewed On Appeal

A. The rejection of claims 1, 3, 4, 6, 7, 9, 11, 12, 14-16, 18 and 20-24 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Nos. 4,359,641 to Franks; 4,692,266 to Costa; and Puseljic *(IEEE Transactions on Nuclear Science*, 1990, Vol. 37(2), pp. 139-143*)*.

B. The rejection of claim 5 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Nos. 4,359,641 to Franks; 4,692,266 to Costa; and Puseljic *(IEEE Transactions on Nuclear Science*, 1990, Vol. 37(2), pp. 139-143*)*, as applied to claims 1, 3 and 4 above, and further in view of Birks (*British Journal of Applied Physics*, 1963, Vol. 14, pp. 141-143*)*.

C. The rejection of claim 19 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Nos. 4,359,641 to Franks; 4,692,266 to Costa; and Puseljic *(IEEE Transactions on Nuclear Science*, 1990, Vol. 37(2), pp. 139-143*)*, as applied to claim 16 above, and further in view of U.S. Patent No. 4,594,179 to Harrah.

D. The rejection of claims 25 and 27 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,359,641 in view of Birks (*British Journal of Applied Physics*, 1963, Vol. 14, pp. 141-143*)*, as further evidenced by Puseljic *(IEEE Transactions on Nuclear Science*, 1990, Vol. 37(2), pp. 139-143).

VII. Argument

A. Rejection of Claims 1, 3, 4, 6, 7, 9, 11, 12, 14-16, 18 and 20-24

Appellant believes that the instant claims are not obvious over Franks or any of the cited references alone or in combination.

The Examiner asserts that Franks teaches a scintillator material having a fluorescent emission of 485 nm. In support of this assertion, the Examiner cites Table 1, line 9 of Franks. Further, the Examiner states that "[e]ven if the solid state fluorescence emission of Coumarin 540 were outside the range of 460-500 nm, this difference would not be significant enough to make the instant claims patentably distinguishable from Franks, because the emission wavelength is an inherent property of the compound."

Appellant notes that Table 1 of Franks shows that emission characteristics of Coumarin 540 vary with solvent identity. Figures 2 and 3 of Franks also show differences in emission dependent on solvent identity. Thus, it appears that the Franks reference teaches that fluorescence characteristics of Coumarin 540 vary and depend on the environment.

In the Advisory Action mailed March 1, 2010, the Examiner states that the Franks reference "teaches that the fluorescent emission of the first scintillator material (Coumarin 540 with a pseudo-cumene as a solvent) has a fluorescent emission of 480, 485, 495, 500 nm, respectively (see Table 1) and the emission wavelength of cocktail of Coumarin 540 and BIBUQ is 485, 490, 500 nm, respectively (see Table 1). The variation of emission wavelength is in a limited range."

Appellant submits that Table 1 of the Franks reference actually shows a much greater variability of fluorescent emission wavelengths for these materials than is acknowledged by the Examiner. Specifically Table 1 discloses emission wavelengths of 480 – 530 nm for Coumarin 540A with pseudo-cumene as a solvent; 540 – 570 nm for Coumarin 540A with benzyl alcohol as a solvent; and 485 – 520 nm for the ternary liquid scintillator including BIBUQ as a primary scintillator, Coumarin 540A as a second scintillator and pseudo-cumene as a solvent.

No teaching is apparent in the Franks reference relating to fluorescent emission of a fluorescent material incorporated in a solid body or solid state member as described in independent claims 1, 9 and 16.

Appellant notes that where "inherency" of a property is alleged, the Examiner must provide rationale or evidence tending to show inherency. (MPEP 2112) "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original, cited in MPEP 2112)

In view of the variability of fluorescence characteristics taught by Franks, Appellant respectfully requests evidence to support a rejection based on inherency if the rejection is to be maintained.

Appellant notes that the Puseljic et al reference also appears limited to teaching characteristics of particular dyes in a single liquid solvent, 1-phenylnapthalene. Appellant submits that neither the Franks

reference nor the Puseljic et al reference provide a teaching of emission characteristics of coumarin dyes in anything other than liquid scintillation materials.

Further, the cited Costa et al reference does not appear to add to any factual analysis of the present claims since this patent also does not describe a solid state member having a fluorescent emission in the range of 460-500 nm.

The cited references, alone or in combination, do not appear to teach all aspects of independent claims 1, 9 and 16 and no *prima facie* case of obviousness is established. Appellant respectfully requests withdrawal of the rejection and allowance of the claims.

B. Rejection of Claim 5

Appellant believes that no *prima facie* case of obviousness is established with regard to the independent claims and that they are allowable. Since dependent claims incorporate all aspects of the independent claims they depend from, Appellant believes the dependent claims are also allowable. Appellant respectfully requests withdrawal of the rejection and allowance of the claims.

C. Rejection of Claim 19

Appellant believes that no *prima facie* case of obviousness is established with regard to the independent claims and that they are allowable. Since dependent claims incorporate all aspects of the independent claims they depend from, Appellant believes the dependent claims are also allowable. Appellant respectfully requests withdrawal of the rejection and allowance of the claims.

D. Rejection of Claims 25 and 27

Regarding independent claim 25, the examiner asserts that the "combined teaching of Franks and Birks teaches a liquid scintillator cocktail comprising Coumarin dye as first scintillator material and PPO or DPA as second scintillator material."

A liquid scintillation cocktail according to claim 25 has a fluorescent emission in the range of 460-500 nm, allowing for detection by both CCD and PMT devices. It is submitted that the subject matter of claim 25 is not obvious over the combined teachings of Franks and Birks since neither Franks nor Birks, nor a combination of these references, provides information that a liquid scintillation cocktail

comprising Coumarin dye as first scintillator material and PPO or DPA as second scintillator material" has a fluorescent emission in the range of 460-500 nm. As detailed above, Table 1 of Franks indicates that scintillator systems including different solvents and scintillators have widely varying fluorescence emission characteristics. Appellant submits that one of skill in the art would have no guidance from the cited references in regard to the particular combination described in claim 25 having a fluorescent emission in the range of 460-500 nm since the references teach variability of fluorescent emission characteristics. Therefore, the cited references, alone or in combination, do not appear to teach all aspects of independent claim 25 and no *prima facie* case of obviousness is established. Appellant respectfully requests withdrawal of the rejection and allowance of the claims.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

Date: May 17, 2010

By: _____

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APPENDIX A

CLAIMS ON APPEAL

1. A medium for a scintillation assay, said medium comprising:

a solid body comprising a first scintillator material, wherein the first scintillator material is a fluorescent Coumarin dye having a Stokes shift of at least 50 nm, wherein the fluorescent emission of the solid body comprising the first scintillator material is in the range of 460-500 nm.

2. The medium of claim 1, wherein said dye has a Stokes shift of at least 100 nm.

4. The medium of claim 1, wherein said medium further includes a second scintillator material.

5. The medium of claim 4, wherein said second scintillator material is selected from the group consisting of: PPO, bis-MSB, DPA, and combinations thereof.

6. The medium of claim 1, wherein said solid body is a solid polymer bead having said Coumarin dye incorporated therein.

7. The medium of claim 6, further including BiBuQ incorporated therein.

9. A method for carrying out an assay for detecting or quantifying a radio nuclide emission, said method comprising the steps of:

providing a scintillation medium comprising a solid body which contains a first scintillator material which is a Coumarin dye having a Stokes shift of at least 50 nm, wherein the fluorescent emission of the solid body which contains a Coumarin dye is in the range of 460-500 nm;

contacting said scintillation medium with an analyte suspected of having said radionuclide therein; and

detecting any scintillation caused in said medium by said radionuclide.

11. The method of claim 9, wherein said Coumarin dye has a Stokes shift of at least 100 nm.

12. The method of claim 9, wherein said solid body is selected from: a polymer bead and a vessel for retaining a liquid scintillation.

14. The method of claim 9, wherein said scintillation medium further includes a second scintillator material.

15. The method of claim 14, wherein said second scintillator material is selected from the group consisting of: PPO, bis-MSB, DPA, BiBuQ, and combinations thereof.

16. A solid state member for a scintillation proximity assay, said member comprising:

a polymeric material having a first scintillator material which is a fluorescent Coumarin dye incorporated therein, said Coumarin dye further characterized in that it has a Stokes shift of at least 50 nm, wherein said solid state member has a fluorescent emission in the range of 460-500 nm.

18. The member of claim 16, wherein said dye is further characterized in that it has Stokes shift of at least 100 nm.

19. The member of claim 16, wherein said Coumarin dye is selected from the group consisting of Coumarin 153, Coumarin 152, and combinations thereof.

20. The member of claim 16, further including a second scintillator material therein.

21. The member of claim 20, wherein said second scintillator material is selected from the group consisting of: PPO, bis-MSB, DPA, BiBuQ, and combinations thereof.

22. The member claim 16, wherein said polymeric material is configured as a bead.

23. The member of claim 16, wherein said polymeric material is configured as a vessel for retaining a liquid.

24. The member of claim 16, wherein said polymeric material is applied to the surface of a vessel configured to retain a liquid.

25. A liquid scintillation cocktail comprising:

a first scintillator material which is a fluorescent Coumarin dye having a Stokes shift of at least 50 nm; a second scintillator material selected from the group consisting of: PPO, bis-MSB, DPA, combinations thereof; and

a solvent for said first and second scintillator materials, wherein said liquid scintillation cocktail has a fluorescent emission in the range of 460-500 nm.

27. The liquid scintillation cocktail of claim 25, wherein said Coumarin dye is further characterized in that has a Stokes shift of at least 100 nm.

APPENDIX B

EVIDENCE

1) *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

17 USPQ2d 1461

Ex parte Levy

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences

No. 90-1864

Decided October 16, 1990

Headnotes

PATENTS

[1] Patentability/Validity - Anticipation - Identity of elements (▶ 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

[2] Patentability/Validity - In general (▶ 115.01)

Patentability/Validity - Anticipation - Prior art (▶ 115.0703)

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

[3] Patentability/Validity - Anticipation - Prior art (▶ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

[4] Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (▶ 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition

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Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

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examiner), applicant appeals. Reversed.

Attorneys

Louis H. Rombach, Wilmington, Del., for appellant.

Judge

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

> 13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*
>
> 25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner are:

Wyeth et al. (Wyeth) 3,733,309 May 15, 1973

Schjeldahl et al.

(Schjeldahl '989) 4,413,989 Nov. 8, 1983
[1]

Schjeldahl et al.

(Schjeldahl '000) 4,456,000 June 26, 1984
[2]

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[1] Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

[2] See footnote 1.

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada,* —F.2d —, 15 USPQ2d 1655 (Fed.Cir. 1990); *In re Bond,* —F.2d —, 15 USPQ2d 1566 (Fed.Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 7 USPQ2d 1315 (Fed.Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 7 USPQ2d 1057 (Fed.Cir. 1988); *Alco Standard Corp. v. TVA,* 808 F.2d 1490, 1 USPQ2d 1337 (Fed.Cir. 1986); *In re Marshall,* 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley,* 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick,* 730 F.2d 1452, 221 USPQ 481 (Fed.Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. §102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states

> he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

> rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

> (a) an expander [3] formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material
>
> **Page 1463**
>
> (column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

[3] Schjeldahl characterizes the catheter balloon as an expander.

> (b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);
>
> (c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);
>
> (d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);
>
> (e) the expander 30 is formed *from* a *biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);
>
> (f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and
>
> (g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article, i.e.,* the expander or catheter balloon, is *not characterized as biaxially oriented.* Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, *i.e.,* injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, [4] which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. [5]

[4] Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

[5] We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber,* 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek,* 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made *of* a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.,* whether the catheter balloon disclosed by Schjedahl is inherently biaxially oriented.

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

> tatements that injection blow molding without stretching will not produce a biaxially oriented article are *true* ... (emphasis supplied).

The examiner goes on, in the same sentence, to state:

> but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

> Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

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upon the examiner. *In re Piasecki,* 745 F.2d 1468, 223 USPQ 785 (Fed.Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King,* 801 F.2d 1324, 231 USPQ 136 (Fed.Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.,* 721 F.2d 1540, 220 USPQ 303 (Fed.Cir. 1983); *In re Oelrich,* 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding,* 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer,* 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

> the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

> ertainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrance equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra; W.L. Gore & Associates, Inc. v. Garlock, Inc., supra; In re Oelrich, supra; In re Wilding, supra; Hansgirg v. Kemmer, supra.* Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is *reversed*. [6]

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[6] There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; *e.g.,* at least about 0.85.

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It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

> Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. [7] ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. [8] Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

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[7] Actually, according to the Final Rejection which is incorporated in the Answer,

> t is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

[8] It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

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[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo,* the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.,* 837 F.2d 1044, 5 USPQ2d 1434 (Fed.Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer, [9] we are constrained to address that issue.

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[9] The noted statement provides:

> Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container.* See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees.* See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman, [10] that the known processes for producing

biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. [11] Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a *biaxially oriented* polymeric catheter balloon. *In re O'Farrell,* 853 F.2d 894, 7 USPQ2d 1673 (Fed.Cir. 1988). The rejection under 35 U.S.C. §103 is also *reversed*.

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[10] We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

[11] We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated

> s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that

> anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

REVERSED.

- End of Case -

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APPENDIX C

RELATED PROCEEDINGS

None.